

REMARKS

In the Office Action, the Examiner withdrew the anticipation rejection against claims 1-3, 5-9, 23, 24, 28, and 30 over U.S. Patent 6,328,969 under 35 U.S.C. §102(b) and withdrew the obviousness rejection against claims 4, 25, and 29 over U.S. Patent 6,328,969 under 35 U.S.C. §103(a). However, the Examiner raised an informality objection, maintained the lack of enablement rejection, and raised an indefiniteness rejection. Each of the objection and rejections is addressed separately below. A 37 C.F.R. § 1.132 declaration is also submitted to support the application. Furthermore, claims 1 and 23 are amended and claims 10-22, 26, 27, and 32 are canceled to facilitate prosecution. Claims 1, 2, 7-9, 23, and 28-31 are pending and under consideration.

In view of the amendments noted above, the remarks provided below, and the 37 C.F.R. § 1.132 declaration submitted herewith, applicant respectfully requests reconsideration of the merits of this patent application.

No extension of time is believed to be necessary and no fee is believed to be due in connection with this response. However, if any extension of time is required in this or any subsequent response, please consider this to be a petition for the appropriate extension and a request to charge the petition fee to the Deposit Account No. 17-0055. No other fee is believed to be due in connection with this response. However, if any fee is due in this or any subsequent response, please charge the fee to the same Deposit Account No. 17-0055.

Claim objections

The Examiner objected to claims 1 and 23 alleging informality with respect to the acronym ISS recited in the claims. In response, applicants have amended claims 1 and 23 to spell out ISS (immune stimulatory sequence) as recommended by the Examiner. Support for the amendment can be found, for example, at the end of paragraph [0016] on page 11 of the application. The objection is believed to have been overcome by the amendment.

Enablement rejection under 35 U.S.C. §112-first paragraph

The Examiner rejected claims 1, 2, and 7-9 under 35 U.S.C. §112, first paragraph alleging that the specification, while being enabling for a method for inducing a humoral or cellular mediated immune response to PAP in a human via intradermal intramuscular,

intravascular, intravenous, or intraarterial administration of a recombinant pNGLV3 construct comprising a polynucleotide sequence encoding a human PAP sequence operably linked to a promoter, and an immuno-stimulatory motif, does not reasonably provide enablement for a method for inducing a humoral or cellular response to PAP in a human to treat prostate cancer. The Examiner indicated that applicant's arguments would most likely be found fully persuasive in overcoming the rejection if the data supplied as Exhibit I and discussed in the response of June 13, 2005 was provided in the form of a declaration under 37 C.F.R. § 1.132.

While applicants respectfully repeat the points raised in the response of June 13, 2005 that for the claimed method to be enabled the method does not necessarily have to be able to cure cancer, a 37 C.F.R. § 1.132 declaration by inventor Dr. Douglas G. McNeel is submitted herewith to facilitate prosecution. As shown in the declaration, immunization with a vector carrying the human or rat PAP gene (pTVG-HP or pTVG-RP) as described in the application elicited both therapeutic (Fig. 1) and protective (Fig. 2) anti-tumor (prostate) responses *in vivo*.

In view of the declaration submitted, applicants respectfully request that the enablement rejection be withdrawn.

Indefiniteness rejections under 35 U.S.C. §112-second paragraph

The Examiner rejected claims 1, 2, 7-9, 23, and 28-30 as being indefinite alleging that claims 1 and 23 can be interpreted to contain either one or three pNGVL3 backbones and further it is not clear if the ISS motif in claim 1 is operably linked to the polynucleotide sequence encoding human PAP. In response, applicants have amended claims 1 and 23 as recommended by the Examiner to clarify these claims. The rejection is believed to have been overcome by the amendments.

Conclusion

Having addressed each issue raised by the Examiner in connection with the amended claims, the claims as amended are believed to be in condition for allowance and a Notice of Allowance is respectfully requested. Should any issues remain outstanding, the Examiner is invited to contact the undersigned at the telephone number appearing below if such would advance the prosecution of this application.

Respectfully submitted,



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